Recommendations of Exclusion of Drugs on Category-H

156. PROF. C. LAKSHMANNA: Will; the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Ministry of Health and Family Welfare has made . recommendation recently to Department of Chemicals as well as Kelkar Committee for exclusion of certain drugs from Category II under existing price control as well as inclusion of certain drugs in category II;

(b) if so, when such a recommendation was sent;

(c) what are the names of drugs recommended for exclusion along-with the basis and justification there' of;

' (d) what are the names of drugs recommended for price control along-with therapeutic indication of each;

(e) whether if Ministry of Health and Family Welfare has also recom mended for shifting of drug from ca tegory I to II; and

(f) if so, what are the names of those drugs and the justification of such recommendation?

THE MINISTER OF. HEALTH AND FAMILY WELFARE (SHRI MOTI LAL VORA): (a) to (f) On the basis of a review made by the Director General of Health Services, recommendations were made to the Department of Chemicals on 9th June, 1988 for the exclusion of Paracetamol from the purview of Category I, on apcount of its not being specifically antimalarial, and Diazepam and cither tranquillizers from the purview of Category II as tranquillizers may not be considered essential for price control. Reclassification of Rifampi-cin from Category I to Category II has also been recommended, the criterion being the high technology involved in the manufacture of the drug requires incentives for production.

Definition of principal drugs for price control

157. SHRI M. KADHARSHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state.

(a) what *is* the definition of principal drugs and in what manner this definition was applied for identification of drugs for price control;

(b.) whether it is a fact that in the policy statement announced in December, 1986, all drugs required for National Health Programmes were to be covered under price control;

(c) whether Tetracycline Hcl. Hydrocortisone, Vitamin A, Folic Acid, Getsimycin, Prednisolong, Iron drugs are principal drugs so far as control of blindness and Child & Maternal Health Programmes are concerned; and

(d if so, what is the differences between one and the other drug, when used for the diseases under these programmes?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI MOTI LAI. VORA): (a) and (b) Essential Drugs distributed and used for specific diseases under eight National Health Programmes were identified for Price Control under the Drugs Price Control Order, 1987.

(c) and (d) Drugs for the Mater-I nal and Child Health Programme are I being evaluated for price control recommendations to the Department of Chemicals. Tetracycline Hcl. and . Hydrocortisone are extensively used under the National. Programme for Control of Blindness.

Permission for marketing of Jbuprofen and Mephenesin combination of FDA Gujarat

158 SHRI M. KADHARSHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state-

(a) whether Ibuprofen in combination with Mephenesin has been allowed ointment from by the Food and Drug Authority Gujarat for marketing in the country;

(b) whether any study or clinical trial was done on this preparation:

(c) if so, what are the details thereoi;

(d) what is the procedure for approval of such products and whe ther all those procedures have been followe:;

(e) what are the names of the co untries -/'here such preparation is "being marketed;

(f) whether it is a fact that drug authorities in States have refused to give permission for such preparation; **and**

(g) if so, what is Government policy in this regard?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI MOTI LAL VORA): (a) to (c) Central Drugs Standards Control Organisation has no information whether Ibuprofen in combination with Mephenesin has been permitted in ointment form by the Food & Drug Authority, Gujarat for marketing.

(d) and (e) As per the Guidelines on introduction of New Drugs combination of known drugs would fall tinder the definition of "New Drugs" and such permission to manufacture and market new drug is required to be granted by the Drugs Controller, India. However, the guidelines are not yet statutory and some States have been licencing certain combination of drugs for marketing.

(f) Central Drugs Standards Control Organisation has no information on the names of the countries where such preparation is being marketed.

(g) Government is making **the** guidelines statutory and permission to manufacture and market all types of combination products would be required to be obtained from the Drugs Controller, India based on the laid down guidelines once these guidelines become statutory.

Marketing of **drag for TB**

159. **SHRI** M. KADHARSHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what are the names of drugs ■ cleared for marketing in the country for treatment of Tuberculosis by drugs Controller of India;

(b) whether it is a fact that**a** number of combinations of one or more

(c) if so, what is the composition of these combinations;

(d) whether any of thes? combina-. tions have been withdrawn from the market or are under process of withdrawal due to irrational combination; and

(e) if so, what are the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI MOTI LAL VORA): (a) The names of antituberculosis drugs approved to- marketing in the country are PAS, Canro-mycin sulphate Ethambutol, Ethionamide, INH, Morazinamide, Prothio-namide, Pyrazinamide, Rifamtiicin, Thiacetazone, Terizidone and Cycloserine .

(b) and (c) The combination of drugs marketed in the country for the treatment of tuberculosis are:

1. Rifampicin 450 mg * INH **300** mg—strip of 4 capsules

2. Etnambutol 800 mg INH 300 membearship of 10 tablets

SHRI ALADI ARUNA *alias* V. ARUNACHALAM (Tamil Nadu); She knows only something in Tamil Nadu. ... *(Interruptions)* ...

THE DEPUTY CHAIRMAN; No cross talking, please.

SHRI SUBRAMANIAN SWAMY: Well, your leader will be soon going ' to America. Don't worry.

SHRI YASHWANT SINHA (Bihar): Has he changed his destination from Italy to America?

SHRIl SUBRAMANIAN SWAMY: Madam, the point is that it is a sign of utter failure that the Government should stand up here and say that in the State of Tamil Nadu they are not in a position to hold elections because peaceful elections are not possible. We made an exception in the case of Punjab. Now, they are saying about Tamil Nadu also. I wonder whether this kind of precedent we' allow them to get away with—whether this kind of thing not be extended ultimately when they face the Lok Sabha General Elections. They may come and say the same thing and ask for another extension there also. But the fact is that there is no disruption of peace in Tamil Nadu. There was an incident, Van-niyar agitation that they talked about was an incident that took place. Since then there had been hardly any incident. First of all, I begin by-saying that the Government is not at all serious in taking the House into confidence because they are not serious. There is no argument about that. Since the consultative con-mittee was set up, I ask the Minister, how many meetings have taken place?

SHRI ALADI ARUNA *alias* V. ARUNACHALAM; It has not been constituted despite our letters.

SHRI SUBRAMANIAN SWAMY: It has been notified that it is going to be constituted. I thought that it was constituted. Well, I also know that no meeting has taken place in the last six months. So, there is no representation in Tamil Nadu. There is no Assembly. Of course, Members of Parliament who come from Congress (I) from Tamil Nadu, they are all, what shall I say, people without voice and hence the people of Tamil Nadu are suffering. Why is it extended for six months? I have moved an amendment saying that it should be 15th September. My friend, Shri Murasoli Maran has said that it should be 30th August. Well, we are from different parties, so there is difference in date. But broadly, we do not think that you need to have six months more because the electoral process is fundamental.

THE DEPUTY CHAIRMAN; Now the House stands adjourned and will meet again at 2.30 P.M.

The House then adjourned for lunch at thirty-one minutes past one of the clock.

The House re-assembled after lunch at thirty one minutes past two of the clock, The Deputy chairman in .the Chair.

STATEMENT BY MINISTER

Accident to train No. 26 Dn. Banga-lore-Trivandrum Express between Sasthankotta and Perinad Stations ofSouthern R ailway on 8-7-1988

THE MINISTER OP STATE OF THE MINISTRY OF RAILWAYS (SHRI MADHAVRAO SCINDIA): Madam, I deeply regret to apprise the House of an unfortunate train accident involving 26 Dn. Bangalore Trivandrum Express at about 12.59 hrs. on 8-7-88 between Sasthankotta and Perinad stations of the Trivandrum Division of Southern Railway.

As a result of the accident 10 out of a total of 14 coaches of the train